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Design and Characterization of Lansoprazole Delayed Release Tables Employing Novel Entric Coating Agents

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ABSTRACT
The present study aimed to enhance the solubility and dissolution rate of Lansoprazole through the preparation of solid dispersions using Hydroxypropyl-β-cyclodextrin (HP-β CD) and to further develop sustained release formulations. Solid dispersions of Lansoprazole were prepared by three different methods physical mixture, kneading method, and co precipitation method in varying drug-to-carrier ratios (1:1 and 1:2). Among these, the co-precipitation method demonstrated the highest enhancement in solubility, followed by the kneading method and the physical mixture, indicating the order: Physical mixture < Kneading method < Co-precipitate method. The optimized formulation (CP-2: Drug: HP β-CD at 1:2 ratio by co-precipitation method) exhibited superior solubility enhancement and dissolution performance. Lansoprazole–HP-β-cyclodextrin complexes showed a significantly higher dissolution rate and efficiency compared to pure Lansoprazole and its conventional capsule forms. These optimized solid dispersions were further utilized to formulate sustained release tablets using different grades of HPMC (K4M, K15M, and K100M) as release-retarding polymers. The pre-compression parameters, including angle of repose, bulk density, tapped density, and compressibility index, indicated excellent flow properties suitable for direct compression. Drug release studies revealed that an increase in polymer concentration led to a reduction in the drug release rate, with formulation F8 exhibiting the most desirable sustained release profile. Kinetic modeling confirmed that the drug release followed zero-order kinetics and obeyed the Higuchi diffusion model, indicating a diffusion-controlled release mechanism.
Keywords: Lansoprazole, solid dispersions, Hydroxypropyl-β-cyclodextrin (HP-β-CD), co-precipitation method, dissolution rate

Introduction

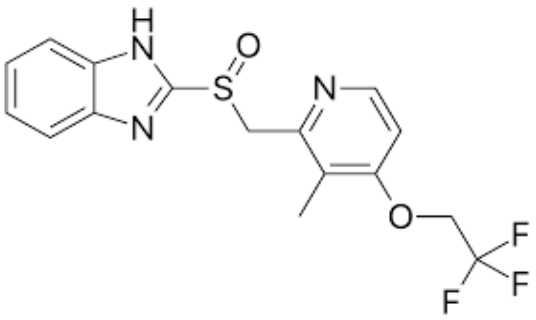

Fig.1: Lansoprazole

Molecular Formula: $C_{16}H_{14}F_3N_3O_2S$ $C_{16}H_{14}F_3N_3O_2S$
Molecular Weight: 369.36 g/mol
IUPAC Name: 2- [[[3-methyl-4- (2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole
Chem Spider ID: 3746
Generic Name: Lansoprazole
Brand Names: FIRST Lansoprazole, Prevacid1
Drug Category: Proton pump inhibitors1
Indications: Treatment of ulcers, erosive esophagitis, and conditions involving excessive stomach acid like Zollinger-Ellison syndrome 2
Pharmacology: Decreases the amount of acid produced in the stomach by blocking the proton pump2
Contraindications: Allergy to lansoprazole, concurrent use with rilpivirine-containing products1
Adverse Effects: Diarrhea, kidney problems, lupus-like syndrome, increased risk of fracture1
Availability: Prescription and over-the-counter (OTC)

Methodology

Table 1: List of Materials Used

S.NO.	MATERIALS	SOURCE
1	Lansoprazole	Supplied By Qualychrome Research Labs Pvt. Ltd.
2	HP-β-Cyclodextrin	S.D. Fine Chemicals Limited, Mumbai
3	Crospovidone	S.D. Fine Chemicals Limited, Mumbai
4	Purified Talc	S.D. Fine Chemicals Limited, Mumbai
5	Magnesium Stearate	S.D. Fine Chemicals Limited, Mumbai
6	Micro crystalline cellulose	S.D. Fine Chemicals Limited, Mumbai

Table 2: List of Equipment's used

S.NO.	EQUIPMENT	MODEL/ SOURCE
1	UV-spectrophotometer	LabindiaUv 3000+
2	Digital Balance	Scale-Tec
3	Digital pH meter	Systronic Electronics, Mumbai
4	Dissolution apparatus	Electrolab TDT-08L
5	Hot air oven	Tempo Instruments &Equipments, Mumbai
6	Hardness tester	Monsanto Hardness Tester
7	Friability test apparatus	Roche Friabilator Electrolab,

		Mumbai
8	Tablet punching machine	Cadmach, Ahmedabad

Analytical Method Development

Preparation of 6.8 phosphate buffer

6.8gms of potassium di hydrogen ortho phosphate was taken in a 1000ml volumetric flask and dissolved with distilled water and make up to 1000 ml with distilled water and adjust pH upto 6.8 with Sodium hydroxide solution.

Determination of Lansoprazole λ_{max} in 6.8 phosphate bufffer

Procedure:

Working standard: 100mg of Lansoprazole was weighed and dissolved in 10ml methanol and then make up to the volume with 6.8 phosphate buffer, it give 1000µg/ml concentrated stock solution.

Dilution 1: From the working standard, 10ml solution was diluted to 100ml with 6.8 phosphate buffer, it will give 100µg/ml concentrated solution.

Dilution 2: From the dilution1, 10ml solution was diluted to 100ml with 6.8 phosphate buffer, it will give 10µg/ml concentrated solutions. This solutions was scanned at range of 200-400nm wavelength light corresponding scan spectrum curve was noted .the corresponding wavelength having highest absorbance is noted as λ_{max}

Construction of calibration curve of Lansoprazole in 6.8 phosphate buffer

Procedure:

Working standard: 100mg of Lansoprazole was weighed and dissolved in 10ml water and then make up to the volume with 6.8 phosphate buffer, it give 1000µg/ml concentrated stock solution.

Dilution 1: From the working standard, 10ml solution was diluted to 100ml with 6.8 phosphate buffer, it will give 100µg/ml concentrated solution.

Dilution 2: From dilution 1, take 0.2, 0.4, 0.6, 0.8, and 1ml of solution was diluted up to the mark with 6.8 phosphate buffer in 10ml volumetric flask to obtain 2, 4, 6, 8 and 10µg/ml concentrated solutions. This solutions absorbance was noted at 238nm.

Preparation of the Solid Dispersions

1. **Physical mixture method:** Drug with polymers in different molar ratios (1:1 and 1:2) were mixed in a mortar for about one hour with constant trituration, passed through sieve No. 80 and stored in desiccators over fused calcium chloride.
2. **Kneading method:** Drug with polymers in different molar ratios (1:1 and 1:2) was taken. First cyclodextrin is added to the mortar, small quantity of 50% ethanol is added while triturating to get slurry like consistency. Then slowly drug is incorporated into the slurry and trituration is further continued for one hour. Slurry is then air dried at 25°C for 24 hours, pulverized and passed through sieve No. 80 and stored in desiccators over fused calcium chloride.
3. **Co-precipitate method:** Drug was dissolved in ethanol at room temperature and polymer was dissolved in distilled water. Different molar ratios of Drug with polymers (1:1 and 1:2) were taken. The mixture was stirred at room temperature, for one hour and then slowly evaporated on a boiling water bath. The inclusion complex precipitated as a crystalline powder was pulverized and passed through sieve No. 80 and stored in a desiccator till free from any traces of the organic solvent.

Evaluation Studies on Solid Dispersions

Drug Content Estimation: Cyclodextrin inclusion complex, a quantity of powder equivalent to 100 mg of Lansoprazole was weighed transferred to a 100 ml volumetric flask. The drug is dissolved in methanol by vigorously shaking for 15 minutes. Then the volume is adjusted to the mark with water and the solution is filtered. From prepared solution take 0.1ml in 10ml volumetric flask and make up to mark with water. The Lansoprazole content was determined by measuring the absorbance at 238nm after appropriate dilution. The drug content was calculated using the standard calibration curve. The mean percent drug content was calculated as an average of three determinations. Calculate the quantity in mg of Lansoprazole in the portion taken by the formula.

***In-vitro* dissolution studies for solid dispersions**

Dissolution Profile:

Apparatus: USP - type II (Paddle)
Medium: 900 ml of 6.8 phosphate buffer
Speed: 50 rpm
Temperature of Medium : 37°C ±1°C
Sampling time points: 5,10,15, 20, 30 , 40, 50 & 60 min
Withdrawn the 5 ml samples through a 0.45µ filter at different intervals of time, suitably diluted and assayed for Lansoprazole at 238nm using a UV spectrophotometer & replace with same volume of buffer. The dissolution experiments were conducted in triplicate

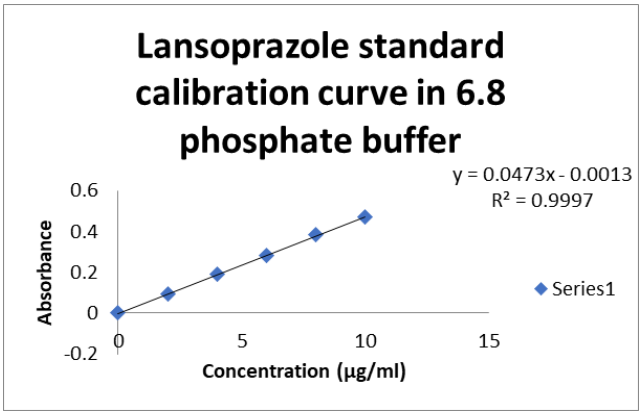

Fig.2: Standard calibration curve of Lansoprazole

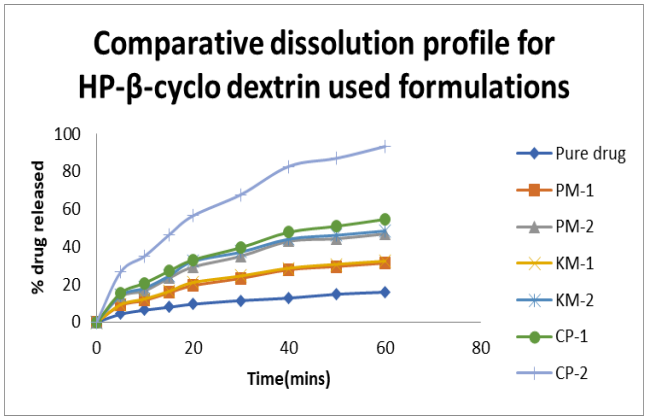

Fig.3: Comparative dissolution profile for pure drug and HP-β-cyclodextrin used formulations

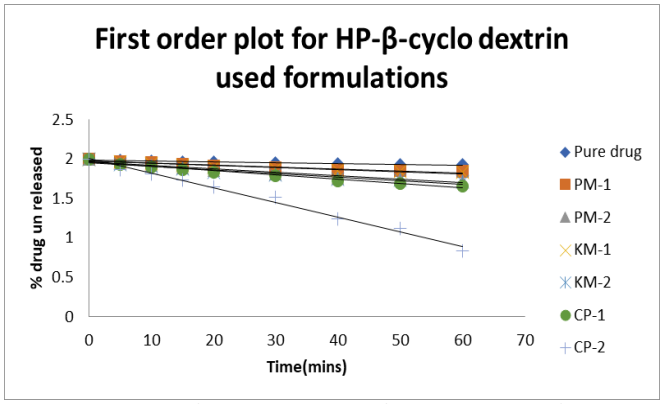

Fig.4: First order plot for pure drug and HP-β-cyclodextrin used formulations

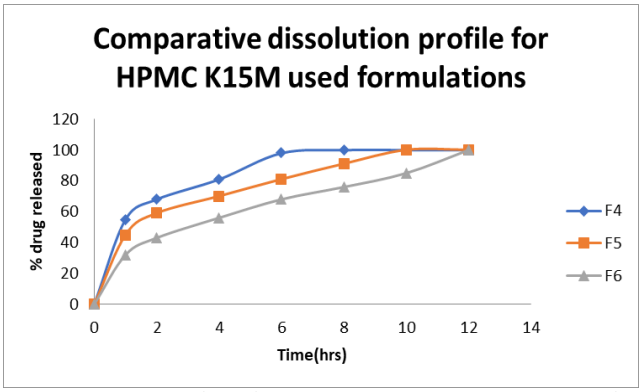

Fig.6: Dissolution profiles of Lansoprazole sustained release capsules for F4, F5 and F6 formulations

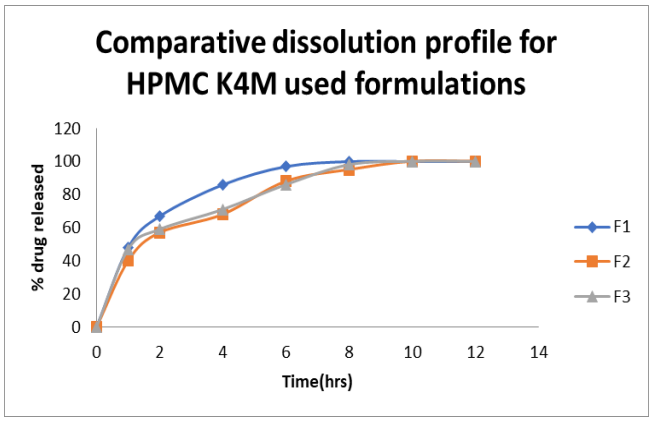

Fig.5: Dissolution profiles of Lansoprazole Enteric coated capsules for F1, F2 and F3 formulations

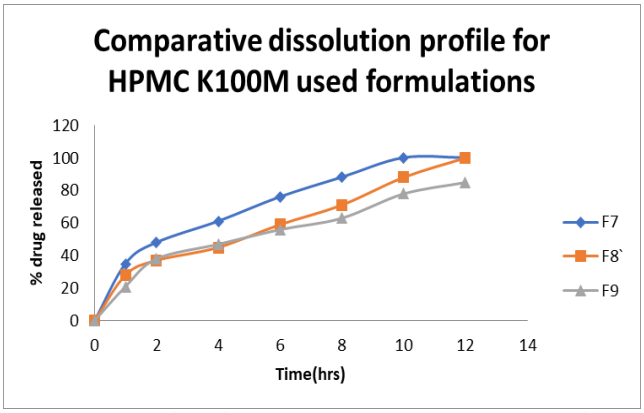

Fig.7: Dissolution profiles of Lansoprazole sustained release capsules for F7, F8 and F9 formulations

Table.3: Pre compression studies of Lansoprazole Enteric coated capsules

Formulations	Bulk density (Kg/cm^3)	Tapped density (Kg/cm^3)	Cars index	Hausners ratio	Angle of repose (˚)
F1	0.37	0.41	9.75	1.1	21.61
F2	0.43	0.52	17.3	1.41	22.62
F3	0.40	0.46	13.0	1.50	22.29
F4	0.44	0.51	13.7	1.25	20.29
F5	0.39	0.47	17.0	1.56	28.23
F6	0.42	0.52	19.2	1.45	23.24
F7	0.41	0.50	18.0	1.50	27.4
F8	0.41	0.51	19.6	1.53	22.26
F9	0.44	0.52	15.3	1.40	23.62

Table 4: Post compression studies of Lansoprazole Enteric coated tablets

Formulation Code	% weight variation	Thickness	% friability	%Drug Content	Hardness (Kg/cm^2)
F1	Pass	4.03	0.14	98.9	6.2
F2	Pass	3.93	0.11	100.2	5.7
F3	Pass	4.06	0.14	101.3	5.56
F4	Pass	4.06	0.15	101.5	6.03
F5	Pass	4.03	0.62	100.1	6.15
F6	Pass	4.1	0.15	100.7	6.63
F7	Pass	3.99	0.23	99.3	6.37
F8	Pass	4.15	0.19	100.2	6.23
F9	Pass	4.0	0.17	99.7	5.98

Table 5: Dissolution data of various enteric coated capsules of Lansoprazole

Time (hrs)	% Drug released								
	F1	F2	F3	F4	F5	F6	F7	F8`	F9
0	0	0	0	0	0	0	0	**0**	0
1	48	40	47	55	45	32	35	**28**	21
2	67	57	59	68	59	43	48	**37**	38
4	86	68	71	81	70	56	61	**45**	47

6	97	88	86	98	81	68	76	**59**	56
8	100	95	98	100	91	76	88	**71**	63
10	100	100	100	100	100	85	100	**88**	78
12	100	100	100	100	100	100	100	**100**	85

Table 6: R2 and N result table for Lansoprazole EC capsules

Formulation code	R2 value				N value
	Zero order	First order	Higuchi	Peppas	
F1	0.819	0.993	0.946	0.964	0.299
F2	0.897	0.981	0.983	0.989	0.379
F3	0.881	0.979	0.976	0.992	0.324
F4	0.812	0.961	0.941	0.977	0.256
F5	0.892	0.968	0.981	0.996	0.327
F6	0.954	0.978	0.996	0.996	0.439
F7	0.941	0.985	0.996	0.997	0.437
F8	0.979	0.966	0.987	0.981	0.503
F9	0.962	0.967	0.994	0.987	0.520

Conclusion

By the three methods employed, order of enhanced solubility is Physical mixture < Kneading method < Co-precipitate method. In all the three methods the drug: solid dispersion ratios, the 1:1< 1:2

- In the solid dispersions used HP-β-cyclodextrin
- The formulation/drug: solid dispersions of CP-2 (Drug: HP-β-cyclodextrin (1:2) & by Co-precipitate method) is having the better solubility enhancement.
- The solubility and dissolution rate of Lansoprazole were markedly enhanced by complexation with HP-β-cyclodextrin.
- Lansoprazole – HP-β-cyclodextrin tablets exhibited significantly higher dissolution rate and efficiency than plain Lansoprazole capsules as well as Lansoprazole – HP-β-cyclodextrin tablets.
- From the above solid dispersions Lansoprazole sustained release formulations are prepared by using HPMC K4M, K15M and K100M.
- The angle of repose, bulk density, tapped density and compressibility index results shown that the formulation is suitable for direct compression method.
- By increasing the polymer, release rate of the drug decreases. F8 gave better release when compared to all formulations.
- By the results we can confirm that order of drug release zero order and the mechanism of drug release from sustained release capsules is Higuchi model.

Conflict of Interests

The authors declare no conflict of interest

Ethics Approval

Not applicable

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AI Tool Declaration

The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

Data Availability

Data will be available on request

References

[1] D.M.Brahmankar, Sunil B. Jaiswal, Biopharmaceutics and Pharmakokinetics, A Treatise, 1st ed, Vallabh Prakasan, Delhi, 2005; 27,5-6.

[2] James Swarbrick., James C Boylan., Encyclopedia of Pharmaceutical Technology, 2nd edition, Vol-1:8.

[3] Christian Leuner., Jennifer Dressmann., Improving drug solubility for oral delivery using solid dispersions. European Journal of Pharmaceutics and Biopharmaceutics, 2000, 50, 47-48.

[4] Leon Shargel., Andrew B.C, Applied Biopharmaceutics and Pharmacokinetics, Appleton-Century-Crofts, 4th Ed, 1985. 134.

[5] H.A. Gare Kani., F. Sadeghi., A. Badiee., S.A. Mostafa and A.R. Rajabisiahboomi., Crystal habit modifications of Ibuprofen and their Physicochemical Characteristics. Drug Development and Industrial Pharmacy, 2001, 27 (8), 803-809.

[6] Leon Shargel., Andrew B.C, Applied Biopharmaceutics and Pharmacokinetics, Appleton-Century-Crofts, 4th Ed, 1985. 135.

[7] D.M.Brahmankar, Sunil B. Jaiswal, Biopharmaceutics and Pharmakokinetics, A Treatise, 1st ed, Vallabh Prakasan, Delhi, 2005; 27,29-30.

[8] Nandita G. Das and Sudip K. Das., Formulation of Poorly Soluble Drugs. Drug Delivery Report Spring/Summer, 2006, 52-55.

[9] Chiou WL and Riegelman SJ. J Pharm Sci 1971; 60: 1283-1297.

[10] James Swarbrick., James C. Boylan., Encyclopedia of Pharmaceutical Technology, 2nd ed, Vol: 1:641-647.

[11] Christian Leuner., Jennifer Dressman., Improving Drug solubility for oral delivery using solid dispersions. European Journal of Pharmaceutics and Biopharmaceutics, 2000, 50, 48-51.

[12] Modi A., Tayade P., Enhancement of dissolution profile of solid dispersion (Kneading) technique. AAPS Pharm Sci Tech., 2006, 7 (3), 1-13.

[13] Devarajan, Padma V, Gore SP. Melt-in-mouth tablets-innovative oral drug delivery systems. Express Pharma Pulse. 2000; 7(1): 16-18.
[14] Reddy L.H., Ghosh B, Rajneesh. Fast dissolving drug delivery systems: A Review of Literature. Indian J Pharm Sci. 2002; 64(4): 331-36.
[15] Kuchekar B S, Bhise S B, Armugam V. Design of fast dissolving tablets. Ind. J. Pharm. Edu. 2001; 35(4): 150-152.
[16] Tetsuya O et al. Design of rapidly disintegrating oral tablets using acid-treated yeast cell wall: A Technical Note. AAPS PharmSciTech 2003; 4(4).
[17] Beatrice P. Formulation design of carbamazepine fast-release tablets prepared by melt granulation technique. Int. J. Pharma 256 (2003) 53–63.
[18] Abdelbary G et al. The preparation of orally disintegrating tablets using a hydrophilic waxy binder. Int. J. Pharma 278 (2004) 423–433.
[19] Okuda Y et al. A new formulation for orally disintegrating tablets using a suspension spray-coating method. Int. J. of Pharma 382 (2009) 80–87.
[20] Sastry SV, Nyshadham JR, Joseph AF. Recent technological advances in oral drug delivery – a review, PSTT 2000; 3(4).
[21] Bandari S, Mittapalli RK, Gannu R, Rao YM. Orodispersible tablets: an overview. Asian J Pharm 2008 Jan [Cited 2008 Nov 9]. Available from URL: http://www.asiapharmaceutics.info.
[22] Santosh Duddelli, Vedavathi T, Ajay Kumar, Zuheb Ur Rahman, R Shireesh Kiran, Formulation And Evaluation Of Risperidone Sustained Release Tablets, Ijpbs, Volume 3, Issue 3, Jul-Sep 2013, 290-298.
[23] Amir Badshah, Fazal Subhan, Khalid Rauf, Nadeem Irfan Bukhari, Kifayatullah Shah, Samiullah Khan, Zia Ahmed, And Ihsanullah Khan, Development Of Controlled-Release Matrix Tablet Of Risperidone: Influence Of Methocel®- And Ethocel®-Based Novel Polymeric Blend On *In Vitro* Drug Release And Bioavailability, Aaps Pharmscitech. 2011 ; 12(2): 797.
[24] Gautam Singhvi, Gautham Gampa, Nilesh Yadav, Vipin Kumar And Ravi Ukawala, Design And Evaluation Of Rapidly Disintegrating Tablets Of Racecadotril With Enhanced In-Vitro Dissolution Achieved By Solid Dispersion Technique, Indian Journal Of Pharmaceutical Education And Research, Vol 47, Issue 3, Jul–Sep, 2013, 56-63.
[25] Sanjay Jain, Sandeep Jain, Ankit Mishra, Gopal Garg And Rahul Kumar Modi, Formulation And Characterization Of Fast Disintegrating Tablets Containing Cefdinir Solid Dispersion, International Journal Of Pharmacy & Life Sciences, Vol. 3, Issue 12: December: 2012, 2190-2199.
[26] B.Stephen Rathinaraj, Ch. Rajveer, Prasanta Kumar Choudhury, Ganesh Sheshrao B And Gajanan V. Shinde, Studies On Dissolution Behaviour Of Sustained Release Solid Dispersions Of Nimodipine, International Journal Of Pharmaceutical Sciences Review And Research, 2010; Volume 3, Issue 1: 77-82.